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Diagnosis of COVID-19

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In December of 2019 the spread of coronavirus disease 2019 pandemic world needs diagnostic system capable of rapid detection of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Measure taken to reduce its spread critically depend on timely and identification of virus-infected individuals by the sensitive and specific method available, i.e. real-time reverse transcriptase Polymerase chain reaction (RT-PCR). There are many commercial kits have recently become available. In this work we performed an independent evaluation of the RealStar. The aim of this study was to compare basic analytical and clinical performance ofselected RT-PCR kits from different manufacturers (Altona Diagnostics, BGI, CerTest Biotec, KH Medical, PrimerDesign, R-Biopharm AG, and Seegene). But here, we use only (ALTONA) for SARS-COV-2. A comparative limit of detection (LoD) evaluation was performed between RealStar. SARS-COV-2 test was also performed 83 primary samples in comparison with WHO-PCR . We conclude that all RT-PCR kits assessed in this study may be used for routine diagnostics of COVID-19 inpatients by experienced molecular diagnostic laboratories.

In results the RealStar SARS-COV-2 was proven a slightly higher than the WHO recommended test with a limit of detection at 625 copies/mL instead of 1250 copies/mL for the WHO-PCR in conditions. The agreement between RealStar SARS-CoV-2 and WHO-PCR on 83 clinical samples was 97.6 % (81/83) with a sensitivity at 97.8 % (45/46) and specificity at 97.3 % (36/37).

In comparison of the RealStar® SARS-CoV-2 test with WHO assay, we observed a slightly better sensitivity of the RealStar test. It provides a durable option for all molecular biology laboratories, with a strong real-life LoD and is compatible with various real-time PCR platforms.

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